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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,860	01/04/2002	Jerome B. Posner	2581.1004-004	4807

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,860	POSNER ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 3 have been amended. Claims 2 and 4-10 have been canceled. Claims 11 and 12 have been added. Claims 1, 3, 11 and 12 are under consideration.

Text of Title 35 U.S. Code not found in this action can be found in a previous action.

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 12 are rejected as lacking adequate written description. Claims 11 and 12 are drawn to four separate sub-genuses of proteins, each sub-genus minimally comprising an antigenic fragment of the recited SEQ ID NO. Although the specification suggests that antigen fragments of the disclosed polypeptides comprise 20, 50, 100 or 200 contiguous amino acids of the disclosed sequences, this limitation is not part of the instant claims. The art recognizes that an antigenic fragment of a protein is a fragment which can be bound by an antibody. This is differentiated from an immunogenic fragment which can elicit an immune response in a given host. The art recognizes that antigenic fragments can be as small as six amino acids. The genus of peptides is claimed as an antigenic fragment, but that qualifier does not impart a functional limitation to the claimed fragments, or the claimed polypeptides which minimally comprise said fragments because any fragment can be antigenic given the appropriate location in a three dimensional structure that would allow access to an antibody containing the paratope which would bind to the antigenic fragment. Thus the genus of claimed peptides is highly variant because the genus tolerates molecules which need only minimally comprise about six contiguous amino acids of SEQ ID NO:4, 7, 9, 11 and 13, and the genus also encompasses proteins which differ widely in function from SEQ ID NO:4, 7, 9, 11 and 13 because specifying that the fragments are antigenic does not establish a specific nexus with the function of SEQ ID NO:4, 7, 9, 11 or 13.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Douvas et al (WO 94/20141).

Claim 11 is drawn in part to an antigenic fragment of SEQ ID NO:11. Douvas et al disclose the peptide EEEEEE (Table III) as Sequence Identifier 6, which is residues 252-257 of the instant SEQ ID NO:11. Douvas et al disclose that this fragment is from the CENP-B antigen which evokes anti-centromere antibodies in individuals having the systemic rheumatic disorder of Scleroderma (Table I).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Douvas et al (WO 94/20141) in view of Campbell (Monoclonal Antibody Technology, 1985, pages 1-32) and Tracey et al (U.S. 6,303,321).

Douvas et al teach the antigenic peptide of Sequence Identifier 6, EEEEEE, said peptide binding auto-antibodies produced from against the CENP-B antigen, which is centromere protein-B. Douvas et al do no teach EEEEEE as a fusion protein. However, Douvas et al teach the generation of either synthetic or murine monoclonal antibodies to RNP epitopes using native immunogens or immunogenic peptides developed as fusion proteins.

Campbell teaches that the potential of monoclonal antibodies in the basic research is considerable because they can resolve a single protein from a complex mixture or indeed a single epitope responsible for a specific function of a complex macromolecule. Campbell also teaches that it is customary now for any group working on a macromolecule to both clone the genes coding for it ad make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular).

It is well known in the art that monoclonal antibodies can be produced by immunization of experimental animals with fusion peptides, as exemplified by Tracey et al (US 6,303,321, column 13, lines 10-22).

It would have been prima facie obvious at the time the claimed invention was made to generate EEEEEE as a fusion protein in order to raise a monoclonal antibody against CENP-B. One of skill in the art would have been motivated by the teachings of Douvas et al on the generation of monoclonal antibodies from fusion proteins to antigenic epitope of the nuclear-protein RNP and the teachings of Campbell regarding the state of the art in generating monoclonal antibodies for research purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
5/19/2005

Karen A. Canella

KAREN A. CANELLA PH.D
PRIMARY EXAMINER